Strategies and Approaches to Optimizing Glioblastoma Therapies: Improving Clinical Outcomes

December 14 – 15 2017 Hilton – Rockville, Rockville MD

Agenda December 14, 2017

2:00 pm – 2:30 pm Welcome and the Meeting Overview

2:00 pm – 2:15 pm Meeting overview—NCI Programs, Meeting Goal and Objectives

Jeff Abrams, MD Mark Gilbert, MD

Dr Abrams to cover broadly the various NCI funded programs, the focus of each and how they interact. What can be improved amongst different mechanisms, their work and portfolios—likely gaps and opportunities.

Dr Gilbert will outline the overarching goal and the objectives of the meeting.

2:15 pm – 2:30 NCI CTEP GBM Portfolio

Bill Timmer, PhD

Bhupinder Mann, MBBS

Stage for the meeting will be set by summarizing the research being conducted by the RO1, PO1 and SPORE grantees (Bill Timmer) and a brief portfolio analysis of the NCTN and ABTC clinical trials (Bhupinder Mann)

2:30 pm -3:50 pm Surgical and Pathological Approaches to GBM

2:30 pm - 2:40 pm Overview of Neurosurgery; Mike Vogelbaum, MD.

2:40 pm – 3:10 pm Format-Free Discussion: What are the evolving roles of neurosurgery—

from maximizing surgical resection, inserting local treatments, to collecting bio-specimens for pharmacodynamic and molecular

biomarker studies.

<u>Discussion Leaders</u> Jeff Bruce, MD Benham Badie, MD Antonio Chiocca, MD

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6:15 pm - 6:20 pm

3:10 pm - 3:20 pm Overview of Pathological Issues; Ken Aldape, MD. Format-Free Discussion: What are the GBM pathology challenges—from 3:20 pm - 3:50 pm molecular markers to working with the neurosurgeon for the optimal specimen processing starting in the OR; dealing with sampling variation and tumor heterogeneity? **Discussion Leaders** Andrew Lassman, MD Fred Lang, MD 3:50 pm - 4:00 pm **BREAK** 4:00 pm - 5:00 pm **Radiation Therapy in GBM Treatment** Overview of Radiation Therapy; Arnab Chakravarti, MD. 4:00 pm -4:10 pm 4:10 PM - 4:20 PM Radiation Sensitizers, Kevin Camphausen, MD 4:20 pm - 5:00 pm Format-Free Discussion: Radiation biology, dose and delivery - can the barriers to success be overcome? Are radiation sensitizers necessary and how best to develop them preclinically? **Discussion Leaders** Hui-Kuo Shu, MD Larry Kleinberg, MD Vinod Gondi, MD 5:00 pm - 6:00 pm **Pre-Clinical Studies** 5:00 pm - 5:15 pm Overview of Novel Pre-Clinical Studies, Jann Sarkaria, MD 5:15 pm - 6:00 pm Format-Free Discussion: What are the best animal models to use? Do orthotopic, or flank models, best recapitulate glioma growth? What are the issues with developing patient-derived xenograft (PDA) models? Are mathematical models of brain tumor growth relevant? How can exosomes be optimized to inform on therapy as it progresses? **Discussion Leaders** Ingo Mellinghoff, MD Jeremy Rich, MD Xandra Breakefield, PhD 6:00 pm - 6:15 pm **Evaluating the NCI Translational Research Efforts in GBM** James H Doroshow, MD Deputy Director for Clinical and Translational Research, NCI

ADJOURN for the DAY; DINNER (on your own)

Agenda December 15, 2017

8:00 am - 8:40 am	Blood-Brain Barrier

8:00 am – 8:10 m Bypassing the Blood Brain Barrier and Other Novel Strategies;

Waldemar Debinski, MD

8:10 am – 8:40 am Format-Free Discussion: What are the most promising agents in the

drug pipeline? What strategies are available for transporting drugs across the blood-brain barrier? What other techniques/approaches can

be used to impact tumor growth?

Discussion Leaders

Jana Portnow, MD Lisa de Angelis, MD Patricia Steeg, MD

8:40 am – 10:40 am Clinical and Translational Studies

8:40 am – 8:50 am Overview of Targeted Agents, Patrick Wen, MD

8:50 am – 9:20 am Format-Free Discussion: What are the most promising agents in the

drug pipeline? How can these agents be brought to clinical trial most

rapidly? How should trial designs be adapted to speed progress?

Discussion Leaders

John de Groot, MD Skip Grossman, MD David Reardon, MD

9:20 am – 9:30 am Overview of Imaging, Dan Barboriak, MD

9:30 am - 10:00 am Format-Free Discussion: Are there available imaging techniques that

should be incorporated into clinical trials? Will ferumoxytol replace gadolinium? When can T1 subtraction maps be used/optimized? What imaging techniques can be used to follow immunotherapy? What non-invasive techniques could be used to differentiate between progression

and pseudo-progression, especially during immunotherapy?

Discussion Leaders

Ben Ellingson, PhD Susan Chang, MD

Tim Cloughesy, MD

10:00 am - 10:10 am Overview of Clinical Trials—Objectives and Designs, Eva Galanis, MD 10:10 am - 10:40 am Format-Free Discussion: Is a generalized Phase I/II design possible for all chemotherapeutic drugs? What trial designs are needed for drugs that measure the OBD (objective biologic dose)? What are the best endpoints to use? **Discussion Leaders** Ying Yuan, PhD Tim Cloughesy, MD Joohee Sul, MD 10:40 am - 11:00 pm Patient Advocates Perspectives—Motivating participation in clinical trials. What benefits do the patients with GBM value most: quality of life, progression free survival, overall survival? Nicole Willmarth, PhD, American Brain Tumor Association David Arons, JD, National Brain Tumor Association 11:00 pm - 12:00 pm LUNCH (on your own) 12:00 pm - 12:10 pm Overview of Immunotherapies, John Sampson, MD 12:10 pm - 12:40 pm Format-Free Discussion: What are the most promising immunotherapeutic approaches? What novel agents are on the horizon? What is the role of dendritic cell vaccines? Is oncolytic viral therapy a viable alternative? Are there other vaccine strategies than can be employed? **Discussion Leaders** Amy Heimberger, MD David Reardon, MD 12:40 pm - 1:10 pm What radical change we should make? Thinking outside the box **Discussion Leaders** Skip Grossman, MD Roger Stupp, MD Al Yung, MD 1:10 pm - 2:00 pm **Conference Summary and Follow-up** 1:10 pm - 2:00 pm Where do we go from here?—a vision for the NCI Program Mark Gilbert, MD Jeff Abrams, MD

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2:00 pm

ADJOURN